REMARKS

Claims 30, 31, 33-38 and 44-49 are pending in the application. Claims 30 and 31 stand rejected under 35 U.S.C. 102(b) as being anticipated by Cragg (2001/49527). Claims 44 and 45 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Cragg '527 in view of Froning (3875595). Claims 33-38 have been allowed. Claims 46-49 were previously indicated to be allowable if rewritten to include all the limitations of the base claim and any intervening claims, with the recent Advisory Action noting that applicants' last amendment to claims 46-48 created §112 2d paragraph issues since the amended claims lack an antecedent basis for certain claim limitations.

1. Claims 46-49.

By this amendment claims 46-48 have been amended to include a limitation of original claim 31 that was inadvertently left out of the prior amended claims. It is now believed that claims 46-49 have been rewritten to include all the limitations of the base claim and any intervening claims, and to cure the lack of antecedent basis.

Claim 49 was not amended since there was no lack of antecedent basis objection to that claim. However, since claim 49 depends from newly amended claim 48, the objection to claim 49 is believed to be obviated by the present amendment to claim 48.

Claims 46-49 are believed to be in a condition for allowance as previously indicated by the Office.

2. Claims 30-31 and 44-45.

Applicants continue to traverse the rejections based on the Cragg '527 reference because Cragg '527 does not disclose implanting a whole disc annulus in an intervertebral disc nucleus space. As indicated in applicants' prior responses, the

Office's contention that paragraph 174 of Cragg '527 discloses implanting a whole disc annulus into a disc space is in error. The relevant language of paragraph 174 of Cragg '527 states:

> In addition, it is also possible to augment a spinal disc by introducing one or more artificial spinal disc implant or other biomaterials to provide a functional disc replacement implant or bone growth materials to effect fusion into the void or cavity that is made within the annulus AF, thereby employing the annulus AF to retain the introduced implants or biomaterials or fusion enhancing materials in place. The annulus AF can itself be used as an envelope to contain the delivered disc augmentation materials comprising spinal disc implant(s), bone growth material or other biomaterials. Optionally, means are provided to contain the disc augmentation materials within the desired space, e.g., by delivering the disc augmentation materials into an additional envelope within the cavity as described above with reference to FIGs. 17 - 20. (Emphasis added.)

It can be seen from the above that paragraph 174 of Cragg '527 does not teach implanting a whole disc annulus in an intervertebral disc nucleus space. Instead, that paragraph merely teaches implanting "one or more artificial spinal disc implant or other biomaterials" into a disc annulus. The annulus referred to in paragraph 174 is the annulus of the disc being repaired, and is not the biomaterial being implanted.

Moreover, the remainder of the Cragg '527 publication fails to teach using a whole disc annulus as a disc implant material. In that regard perhaps the most relevant portion of Cragg '527 is paragraph 160, which states:

> In this case, the biomaterial filling the envelope 80 is a material that is capable of being introduced to the site of a joint by minimally invasive means, and be hydrated or cured in place to provide desired physical-chemical properties as described, for example, in the above-referenced '326, '454, '220 and '736 patents. A hydrogel can be injected into the envelope 80 in a liquid or dry particulate form or in microspheres or beads in the manner shown in FIG. 18. A preferred hydrogel is formulated as a mixture of hydrogel polyacrylonitrile or any hydrophilic acrylate derivative with a unique multiblock copolymer structure or any other hydrogel material having the ability to imbibe

> and expel fluids while maintaining its structure under various stresses. For example, the hydrogel can be formulated as a mixture of polyvinyl alcohol and water. The hydrogel core formed within the envelope 80 will swell as it absorbs fluids through the porous fabric wall of the envelope 80 much like a native nucleus. The hydrogel core has a time constant of swelling which is highly similar to that of the natural nucleus and will thus experience a 5-30% and preferably a 15-20% volume change depending on load over the course of 2-8 (preferably 4-8) hours. When fully hydrated, the hydrogel core will have a water content of between 25-65%. The hydrogel material of the preferred embodiment is manufactured under the trade name Hypan.RTM. by Hymedix International, Inc. In addition, any of the hydrogels and solvents identified in the above-referenced '326 patent may be employed to fill the envelope 80.

In view of the above it is respectfully submitted that the cited prior art does not teach implanting a whole disc annulus into an intervertebral disc nucleus space as required by the pending claims. Accordingly, the rejection under §102 should be withdrawn.

In the Advisory Action that replied to the most recent of applicants' responses, the Office stated simply that "the examiner is not persuaded regarding the Cragg reference." The Advisory Action did not dispute the accuracy of the applicants' quotations from Cragg, nor did the Office indicate any other statements from Cragg '527 that would support a different view of the reference. In order to frame the issues for a potential appeal, it is respectfully requested that the Office identify the specific portions of Cragg '527 that are believed to disclose implanting a whole disc annulus into an intervertebral disc space as presently claimed. In the absence of such a specific teaching, the rejection under §102(b) based on Cragg '527 should be withdrawn.

For the reasons set for the above, favorable reconsideration of the application is respectfully requested.

Respectfully submitted,

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